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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,052	01/28/2002	Joseph M. Patti	P07069US04/BAS	3946

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EXAMINER
LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No.	Applicant(s)	
	10/056,052	PATTI ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *27-31* is/are objected to.

8)☒ Claim(s) *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, 19, and 23-24, 26-37, drawn to antibodies, and antibody fragments)that bind to the S. aureus ClfA protein, classified in class 530, subclass 388.2.

II. Claim 18, drawn to methods of diagnosing an S. aureus infect by contacting a sample with an antibody, classified in class 435, subclass 7.2.

III. Claim 20, drawn to methods of treating or preventing S. aureus infection by administering an antibody to a subject, classified in class 424, subclass 139.1.

IV. Claim 21, drawn to a method of inducing an immunological response in a subject by administering a ClfA protein to a subject, classified in class 514, subclass 2.

V. Claim 22, drawn to methods of identifying monoclonal antibodies to a ClfA protein by contacting a sample suspected of having such proteins with a ClfA protein, classified in class 514, subclass 2.

VI. Claim 25, drawn to an isolated active fragment of the A domain of an S. aureus ClfA protein, classified in class 514, subclass 2.

For each of Groups I-VI above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-V and one of inventions (A)-(C). Subgroups (A) to (C) represent the elected invention wherein the targeted, immunogenic, or active ClfA protein is selected from:

(A) the Clf40 protein (SEQ ID NO: 2, or the protein encoded by SEQ ID NO: 1),
(B) the Clf33 protein (SEQ ID NO: 4, or the protein encoded by SEQ ID NO: 3), and
(C) the ClfA N3 protein.

For each of Groups I-III above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-VI, and to one of Groups (A)-(C), and, if one of Groups I-II was elected, to one of inventions (H1) to (H6) and to one of inventions (L1)-(L7). The combined election of one of (H1)-(H6) and (L1)-(L7) represent the elected invention through an antibody with an identified combination of a light and heavy chain variable region. The variable regions are as follows:

The heavy chain variable regions are represented by antibodies wherein the region comprises :

(H1) SEQ ID NO: 8, or the sequence encoded by SEQ ID NO: 7;
(H2) SEQ ID NO: 12, or the sequence encoded by SEQ ID NO: 11;
(H3) SEQ ID NO: 16, or the sequence encoded by SEQ ID NO: 15;
(H4) SEQ ID NO: 20, or the sequence encoded by SEQ ID NO: 19;
(H5) the sequence RYSVH; or
(H6) the sequence MIWGGGNTDYNSALKS.

The light chain variable regions are represented by antibodies wherein the region comprises :

(L1) SEQ ID NO: 6, or the sequence encoded by SEQ ID NO: 5;
(L2) SEQ ID NO: 10, or the sequence encoded by SEQ ID NO: 9;
(L3) SEQ ID NO: 14, or the sequence encoded by SEQ ID NO: 13;
(L4) SEQ ID NO: 18, or the sequence encoded by SEQ ID NO: 17;
(L5) the sequence KSSQSVLYSSNQKNYLA;
(L6) the sequence WASTRES; or
(L6) the sequence HQYLSSYT.

The inventions are distinct, each from the others, for the following reasons:

2. The inventions of Groups (A) to (C) are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. See MPEP § 806.05(d). In the instant case, the different inventions relate to inventions comprising, targeting, or using, a different part of the ClfA protein. Each of these inventions has the same separate utility as the combination. As each of these separate inventions has an independent utility, the inventions are distinct.

3. The inventions defined by the election of one of (H1)-(H6) and one of (L1)-(L7) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use

together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions relate to antibodies with different variable regions. Each of these antibodies either targets a different regions of the ClfA protein, or has uses a different sequence to bind that region (a different mode of operation). As the different antibodies have different modes of operation and different structures, they are distinct from each other.

4. The inventions of Groups I-III are unrelated to the inventions of Groups IV-VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions relate to compositions comprising, and methods of using different types of molecules- immunogenic proteins, and antibodies that bind to them. As the different molecules perform different functions and achieve different effects, they are not related.

5. The invention of Group VI is related as product and process of use with the inventions of Groups IV and V. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, as the proteins of Group IV may be used in either of the methods of Group V or VI, the product is distinct from either method.

6. The inventions of Group I is related as product and process of use with the inventions of Groups II and III. The inventions can be shown to be distinct if either or both of the following

can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, as the antibodies of Group I may be used in either of the methods of Group II or III, the product is distinct from either method.

Sequence Rules Compliance

7. The specification and claims 27-31 are objected to for referring to protein or nucleic acid sequences without also identifying them by the sequence identifier assigned to them in the sequence listing as required by 37 CFR 1.821(d). See e.g., pp. 34-37, 39, 41-42; and claims 27-31. The examiner would like to bring the applicant's attention to the following excerpt from MPEP §2422.03:

> 37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. This requirement is also intended to permit references, in both the description and claims, to sequences set forth in the "Sequence Listing" by the use of assigned sequence identifiers without repeating the sequence in the text of the description or claims. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need not be separately presented in the "Sequence Listing." Where a sequence is embedded in the text of an application, it must be presented in a manner that complies with the requirements of the sequence rules.

The applicant is therefore required to amend the specification to comply with 37 CFR 1.821(d). With regards to the claims identified above, it is noted that the applicant may identify such fragments by referring to sequence positions in an identified sequence. See MPEP §2422.03 (discussing reference to variants of a disclosed sequence).

Conclusion

8. Because these inventions are distinct for the reasons given above, have acquired a separate status in art because of recognized divergent subject matter and different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

9. It is here noted that some of the restrictions requirements made above fall within the scope of PTO Linking claim practice. In accordance with this practice as described in MPEP 809.03, linking claims will be considered with the elected invention. If the elected invention is found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn.

10. Applicant's attention is hereby directed to the following is a recitation of M.P.E.P. §821.04 regarding the restriction of claims to a product and processes of using the product,

Rejoinder:

> Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.
>
> Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. Amendments submitted after final rejection are governed by 37 CFR 1.116. Process claims which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03). Amendments submitted after allowance are governed by 37 CFR 1.312. Process claims which depend from or otherwise include all the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

> "However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

In accordance with M.P.E.P. §821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner
February 10, 2003

JAMES HOUSEL 2/10/03
SUPERVISORY PATENT EXAMINER
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